

Specification

Product name:	Carboplatin, Diammine-(1,1-cyclobutanedicarboxylato)platinum(II)	Ph. Eur.
Formula:	Pt(C ₄ H ₆ (COO) ₂)(NH ₃) ₂	
Heraeus Ident-No.:	89730036	
The product is in compliance with Ph. Eur. and Heraeus specification.		

No.	Parameter	Specification	Method
1.	Characters		
a	Appearance	white, crystalline powder	Ph. Eur.
b	Solubility	sparingly soluble in water, very slightly soluble in acetone and in ethanol (96%)	Ph. Eur.
2.	Identification		
a	IR spectrum	conforms to standard	Ph. Eur.
3.	Tests		
a	Appearance of solution	clear and colourless	Ph. Eur.
b	Impurity B: 1,1-Cyclobutanedicarboxylic acid [wt.%]	NMT 0.5	Ph. Eur.
c	Acidity [ml]	NMT 0.7 ml 0.01M NaOH	Ph. Eur.
4.	Related substances acc. Ph. Eur.		
a	Impurity A: Cisplatin [area%]	NMT 0.25	Ph. Eur.
b	Any unspecified impurity [area%]	NMT 0.10	Ph. Eur.
c	Total impurities [area%]	NMT 0.5	Ph. Eur.
5.	Ammonium [ppm]	NMT 100	Ph. Eur.
6.	Chlorides [ppm]	NMT 100	Ph. Eur.
7.	Nitrate [ppm]	NMT 180	Heraeus
8.	Potassium [ppm]	NMT 10	Heraeus
9.	Platinum [wt.%]	52.4 - 52.7	Heraeus
10.	Loss on drying [wt.%]	NMT 0.5	Ph. Eur.
11.	Methanol [ppm]	NMT 500	Heraeus
12.	Assay [wt.%] (dried substance)	98.0 - 102.0	Ph. Eur.
13.	Microbial bioburden		
a	TAMC: Total aerobic microbial count [CFU/g]	NMT 100	Ph. Eur. / USP
b	TYMC: Total combined yeast and mould count [CFU/g]	NMT 50	Ph. Eur. / USP
c	Bacterial endotoxins [EU/mg]	NMT 0.13	Ph. Eur. / USP

Specification

Product name:	Carboplatin, Diammine-(1,1-cyclobutanedicarboxylato)platinum(II)	US
Formula:	Pt(C ₄ H ₆ (COO) ₂)(NH ₃) ₂	
Heraeus Ident-No.:	89730036	
The product is in compliance with USP and Heraeus specification.		

No.	Parameter	Specification	Method
1.	Characters		
a	Appearance	white, crystalline powder	Heraeus
2.	Identification		
a	IR spectrum	conforms to standard	USP
b	HPLC retention time	conforms to standard	Heraeus
3.	Tests		
a	Crystallinity	meets the requirements	USP
4.	Related substances acc. Heraeus		
a	Cisplatin [wt.%]	NMT 0.05	Heraeus
b	1,1-Cyclobutanedicarboxylic acid [wt.%]	NMT 0.15	Heraeus
c	Cyclobutanemonocarboxylic acid [wt.%]	NMT 0.15	Heraeus
d	Greatest unknown impurity [wt.%]	NMT 0.10	Heraeus
e	Total related substances [wt.%]	NMT 0.5	Heraeus
5.	Nitrate [ppm]	NMT 180	Heraeus
6.	Potassium [ppm]	NMT 10	Heraeus
7.	Platinum [wt.%]	52.4 - 52.7	Heraeus
8.	Silver [ppm]	NMT 10	Ph. Eur.
9.	Loss on drying [wt.%]	NMT 0.5	USP
10.	Water-insoluble matter [wt.%]	NMT 0.5	USP
11.	Methanol [ppm]	NMT 500	Heraeus
12.	Transmittance (440nm) [%]	NLT 97.0	USP
13.	pH	5.0 - 7.0	USP
14.	Particle size [µm]	100% NMT 500	Heraeus
15.	Assay [wt.%] (on dried basis)	98.0 - 102.0	Heraeus
16.	Microbial bioburden		
a	TAMC: Total aerobic microbial count [CFU/g]	NMT 100	Ph. Eur. / USP
b	Bacterial endotoxins [EU/mg]	NMT 0.13	Ph. Eur. / USP